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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/556,804

01/18/2006

Luke Alphey

129-05

1467

23713

7590

05/12/2010

GREENLEE WINNER AND SULLIVAN P C

4875 PEARL EAST CIRCLE

SUITE 200

BOULDER, CO 80301

EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

05/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,804	Applicant(s) ALPHEY, LUKE	
	Examiner SHANON A. FOLEY	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 14-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 14-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/20/08 and 3/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species Asian tiger mosquito in the reply filed on June 29, 2009 is acknowledged. The traversal is on the ground(s) that the special technical feature links the various species and requests reconsideration.

Applicant's traversal is found persuasive and the restriction is withdrawn. Claims 1, 2 and 14-49 are pending and under consideration.

Claim Objections

Claims 2, 21, 37 and 44 are objected to because of the following informalities:

Claim 2 refers to "the trait" and "that trait" in lines 1, 2 and 3 and is dependent on claim 1. Claim 1 differentiates two traits by prefacing each with "non wild type" or "wild type counterpart". While the meaning of claim 2 is understood, it would be more readily interpretable if "the trait" and "that trait" recited in lines 1, 2 and 3 were prefaced by the same terms used in claim 1.

Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 states that the genetic trait is non wild type and the sexually compatible individuals are wild type for the genetic trait. These limitations are already required by claim 1, from which claim 21 depends.

Claims 37 and 44 lack periods at the end of the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 14, 19-24 and 26-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the spread of a non-wild-type genetic trait in insect pests by introducing sexually compatible individuals substantially homozygous for a conditional dominant-lethal gene counterpart to the wild-type trait in insect pest populations, does not reasonably provide enablement for a method of inhibiting the spread of a non-wild-type genetic trait in other organisms, such as mammals, fungi, yeast and bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The scope of the claims encompasses inhibiting the spread of any non-wild-type genetic trait in any organism. The non-wild-type trait of interest in the instant invention is resistance in insects to pesticidal toxins expressed by plants or administered to plants, see paragraphs [0008, 0012, 0021] and the working examples beginning in paragraph [0136] of the instant published application, USPGPub 2006/0275276. However, the scope of the instant claims encompasses suppressing any non-wild-type trait in any non-human organism. The non-wild-type traits encompassed by the claims may be achieved through natural genetic reassortment and/or an adaptation to environmental pressures that occurs during natural selection. The instant non wild-type traits are not limited to insecticidal adaptations to phytotoxins. There is no guidance or

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discussion provided in the instant disclosure for how one skilled in the art could inhibit natural selection of non wild-type genetic traits in any non-human organism except insects. There is also no teaching in the prior or current state of the art that provides guidance or an impetus for eliminating or inhibiting the spread of any wild-type genetic trait in any non-human organism. For these reasons, it is determined that the instant claims are not commensurate in scope for inhibiting the spread of any non-wild-type gene in any non-human organism claimed and would require an undue quantity of experimentation to make and/or use the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 14-21, 31 and 33-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Alpey et al., hereinafter “Alpey”, (WO 01/39599, cited in the IDS).

Alpey anticipates a method of inhibiting the spread of wild-type genes in insects, such as medflies and malaria mosquitoes, by distributing insects homozygous at more than one locus expressing conditionally suppressible dominant lethal non-wild-type counterpart genes selective for females. See claims 1-3, 6, 7, 9-11, 13, 14, 17, 20-23 and 27. Also see pages 3-9 and 22-27 of the disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alphey *supra*.

See the teachings of Alphey above. Alphey does not specifically discuss the calculations required to deduce the optimal quantities of genetically engineered insects introduced into the target population. However, Alphey does discuss of introducing a genetically engineered adults at a single point in time or introducing a normal population of genetically engineered individuals to prolong exposure to the wild-type population, see the full paragraph on page 5 of the disclosure.

Releasing a specific percentage of recombinant individuals to reduce a wild-type trait or genes would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The adjustment of particular conventional working conditions as well as affecting the desired effect, is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 22-26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alphey as applied to claims 1, 2, 14-21, 27-31 and 33-49 above, and further in view of Buman et al. (US 6,338,040), hereinafter as "Buman".

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See the teachings of Alphey above. Alphey does not teach or suggest the genetic trait to be reduced is resistance to a pesticide or treating resistance with a toxin expressed in a food crop and providing refugia.

Buman teaches wide application of crops expressing Bt toxins and refugia to delay the resistance to Bt toxin, see Figure 1A and column 1, line 49 to column 2, line 6 and claims 1, 2 and 10.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the genetic engineering method of Alphey with crops expressing the Bt toxin and refugia to reduce the incidence of insect resistance to pesticides. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining the methods of Alphey and Buman since Alphey teaches that the method to reduce wild-type genotypes in insects and resistance to the Bt toxin is a wild-type modification developed in insects.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Alphey et al. (Journal of Economic Entomology. 2007; 100 (5): 1642-1649).

Fu et al. (Nature Biotechnology. 2007; 25 (3): 353-357).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
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